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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,545	02/12/2004	Kristian DiMatteo	10123/04501	5754

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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,545	DIMATTEO ET AL.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *14,15,22 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,16-21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/12/2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/10/04, 7/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species:

Species A: Figs. 1-6

Species B: Fig. 7

Species C: Fig. 11

Species D: Fig. 12

Species E: Fig. 13

The species are independent or distinct because each species is discloses a differently shaped distal tip for a catheter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Fig. 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations

of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Patrick Fay on 4/18/06 a provisional election was made without traverse to prosecute the invention of Species B, claims 1-21 and 23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14 and 15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

The drawings are objected to because the lumen in Figs. 5 and 6 labeled as (102) does not match what is disclosed in paragraph [0013], according to which, the lumen should be labeled as (104). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be

removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: the word "more" in the fifth line of paragraph [0009] should be changed to "mode". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 16-21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Quinn (US Patent No. 6,461,321). Quinn discloses a distal tip for a catheter (Fig. 5) comprising: first (59a) and second (59b) lumens extending there through, wherein in an operative configuration, the first and second lumens are coupled

to first (27a) and second (27b) lumens of a dual lumen catheter (24); a first opening (37) fluidly connected to the first lumen (59a) for inflow of fluid from a body lumen into which the distal tip is inserted in a normal mode of operation and for outflow of fluid thereto in a reverse mode of operation (col. 3, lines 7-11 and col. 7, lines 57-61); a second opening (89) fluidly connected to the second lumen (59b), the second opening being disposed distally from the first opening and separated therefrom by a selected stagger distance for outflow of the fluid therefrom when the catheter is in the normal mode of operation and for inflow of fluid from the body lumen in a reverse mode of operation (col. 3, lines 7-11 and col. 7, lines 57-61); a contoured flow deflection element (93) directing, in the reverse mode of operation, outflow from the first opening away from the second opening (col. 7, lines 57-61 state that if the flow is reversed such that blood flows out through the first opening then the inflow of blood through the second opening does not mix with the outflow of blood because the two are staggered apart, and the flow of blood out from the first opening (37) would inherently hit the ramped portion of the bolus (20) and be deflected upward and away from the second opening); a contoured outlet portion (78) of the second opening reducing an outflow velocity therefrom in the normal mode of operation (col. 7, lines 53-56).

Quinn further discloses that the first and second openings are disposed on opposite sides of the distal tip (Fig. 5 and also see col. 3, lines 41-47) thereof. Quinn further discloses that the first and second openings have orifices (37 and 89) extending in planes angled with respect to a longitudinal axis (X) of the distal tip (as disclosed in Fig. 5). Quinn also discloses that the contoured flow deflector element (57) is adapted

to direct outflow from the second opening (89) away from the first opening (37) in the normal mode of operation (Fig. 5 shows that the fluid flow would be directed along lumen 56 and would be then be directed outwards and downwards in the opposite direction from the first opening). Quinn also discloses that the distal tip is comprised of an atraumatic tip. Quinn further discloses that the first opening includes a first ramp portion (area nearest 20 in Fig. 5) that inherently deflects outflow therefrom away from a longitudinal axis of the distal tip when in the reverse mode of operation (col. 7, lines 57-61). Quinn further discloses that the second opening (89) includes a second ramp portion (78) deflecting outflow from the second opening away form a longitudinal axis (X) of the distal tip in the normal mode (Fig. 5). Quinn also discloses that the second opening comprises an expanded section (Fig. 2, 71) increasing an exit plane cross sectional area of the second orifice (Fig. 5 also shows that the second orifice (89) expands upwards above the X-plane to create the expanded area). Quinn also discloses that the first and second lumens have D-shaped cross sections (Fig. 7). Quinn further discloses that the first ramp (near 20) is aligned with the first opening (37) and the second ramp (78) is aligned with the second opening (89) and there is an atraumatic distal tip (Fig. 2, 99). Quinn further discloses that the maximum radial dimension of the contoured bolus (99) is less than a radius of a catheter to which the distal tip is to be coupled (col. 6, lines 60-65).

Quinn further discloses a flow control tip for a multi-lumen catheter comprising: an attachment portion (Fig. 5) adapted to fluidly connect to a distal portion of a catheter (24). Fig. 5 discloses that the flow control tip (93) attaches to the distal end of the

catheter (24) at the region disclosed as (34), also see col. 5, lines 49-51. Quinn further discloses a contoured bolus (93) defining at least a portion of an inlet (37) and an outlet (89) of the distal tip so that, when coupled to a catheter, the inlet is coupled to a first one of the catheter lumens (59a) and the outlet is coupled to a second one of the catheter lumens (59b), and a flow deflector (78) directing fluids exiting the inlet in a first mode away from the outlet, wherein the contoured bolus defines a specified stagger distance between the inlet and the outlet. Quinn also discloses that the contoured bolus further comprises a second flow deflector (near 20) directing fluid exiting the outlet in a second mode away from the inlet (col. 7, lines 57-61). Quinn also discloses that the inlet and the outlet are formed on opposite surfaces of the contoured bolus (Fig. 5, also see col. 3, lines 41-47). Quinn further discloses that the flow deflector comprises a ramp (near 20) disposed adjacent an inlet opening (37). Quinn also discloses that the contoured bolus defines an expanded section (Fig. 5 discloses that directly above element 91, the lumen 56 expands upwards so that it expands above the x-axis) which increases an exit plane cross-sectional area of the outlet. Quinn further discloses that the size of the expanded section is selected to reduce an exit pressure (col. 7, lines 51-57). Quinn also discloses that the attachment portion is adapted for attachment to the catheter by thermal bonding (col. 5, lines 51-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US Patent No. 6,461,321) in view of Dasse et al. (US Patent No. 5,171,216). Quinn discloses the device substantially as claimed, however, Quinn does not disclose expressly that the stagger distance between the openings is between 1 and 1.5 cm. Dasse, however, discloses a distal tip of a catheter with a stagger distance between the openings (Fig. 3, 14 and 16) that can be anywhere in the range of 1-4 cm (see col. 5, lines 7-13). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Quinn with the stagger distance as specified by Dasse in order to provide an optimal distance between the openings such that mixing of the blood does not occur, yet also to ensure that the distal tip of the catheter can still be maneuverable within a vascular system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KEVIN SIRMONS
PRIMARY EXAMINER

Kevin C. Sirmons